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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,495	06/24/2005	Geoffrey Lee	UST 02 (P66419)	5458

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EXAMINER	
MAEWALL, SNIGDHA	
ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
12/15/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/502,495	LEE ET AL.	
	Examiner	Art Unit	
	SNIGDHA MAEWALL	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-7,9,13 and 14* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-7, 9 and 13-14* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/04/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/18/09 has been entered.

Previous Rejections

Applicants' arguments, filed 12/18/09 have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Information Disclosure Statement

The information disclosure statement filed 05/04/09 has been considered. An initialed copy is enclosed.

Terminal Disclaimer

The provisional nonstatutory obviousness-type double patenting rejections made over claims 1-12 of copending Application No. 10/332547 are hereby withdrawn in light of Applicant's submission of terminal disclosure. The terminal disclaimer was approved on 12/05/11 and has been placed on records.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 contains the trademark/trade name Eudragit ® NE Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe (ethyl acrylate-

methyl methacrylate- copolymerisate) and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 9 and 13-14 are rejected Under 35 U.S.C. 103(a) as being unpatentable over WO 95/05813 (WO) in view of **Gueret (USP 6,280,765).**

WO 813 teaches pharmaceutical compositions comprising aminolevulinic acid (ALA) and its salts such as hydrochloride salts applied to skin or other dermal membrane, such as in the form of a skin patch (abstract) for treating cutaneous conditions such as those recited in instant claims 11 and 12 (page 10, L 23-29). WO teaches the composition is anhydrous. WO recognizes that ALA is unstable in fluid vehicles and degrades rapidly, particularly at higher pH (page 2, last paragraph). Like the instant disclosure, WO also desires a stable ALA preparation for dermal administration (page 3, L 5-20) and suggests adding a stabilizing amount of a solid carrier to prevent or minimize degradation of ALA (page 4, L 13-23). With respect to administration, WO teaches adhesive matrix and reservoir devices i.e., pressure sensitive adhesive matrix made of polymers such as acrylics, silicones etc. (page 7-

page 8). WO teaches incorporating 0.5% to 50% ALA in the matrix, as in the instant claim 6 (page 7, L 24-25).

WO fails to teach crystalline ALA suspended in the matrix and also lacks the particle size of 20 microns to 200 microns.

‘765 teach a cosmetic transdermal patch for controlled delivery of water soluble as well as water insoluble active agents simultaneously, and excellent adhesive power of the patch to the skin surfaces (abstract). The patch of ‘765 comprises a hydrophobic polymer that contains particles of water soluble active agent, particles of water insoluble active agent and particulate water absorbing agent (abstract). The water soluble drug particles of ‘765 are not dissolved and instead added to oil particles and hence forms a suspension or dispersion (as required in the instant claims). For the particulate water soluble substances, particle sizes and the amount of the water soluble substance, see col. 4, L 50-58, claim 12 and claim 13 of ‘756, wherein the particle sizes of the active agent range from 0.2microns to 0.5mm (200 nm to 500 microns) and the amount of the drug is between 0.2% to 20%. Thus, the amounts and the particle sizes of water soluble drugs taught by ‘765 are within the claimed ranges. ‘756 do not teach ALA or esters of the instant invention but teaches that a wide range of water soluble substances may be used (col. 4, L 24-36). ‘765 also states that said transdermal patch enables preparation of a stable combination of particles of a water soluble compound, which is unstable in aqueous medium or in the open air, without the risk of degradation of the active compound (col. 2, L 40-51).

Accordingly, it would have been obvious to one of an ordinary skill in the art at the time of the instant invention to employ the water soluble ALA salt of WO '813 in the form of microparticle having a size range of anywhere between 200 nm to 500 microns in the polymer matrix taught by WO 813 because '765 suggests a water soluble drug, which otherwise is stable in aqueous solution, may be added in the transdermal patch in a particulate form with a size of 200 nm to 500 microns. A skilled artisan would expect that the soluble particulate drug would retain its efficacy and stability even in combination with a water insoluble drug. In this regard, the examiner notes that the polymer matrix of '765 is made of silicone polymers (like instant claim 3).

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/05813 (WO 813) in view of US 6,280,765 to Gueret (765) as applied to claims 1-6, 9 and 13-14 above, and further in view of Xlong et al. (US PG pub. 2004/0202705 A1).

WO as discussed above teaches acrylic polymers such as Eudragit but does not teach the claimed Eudragit NE and tributyl citrate. '765 as discussed above fail to teach the claimed Eudragit NE and tributyl citrate.

Xlong et al. discloses an adhesive matrix patch for transdermal delivery with permeation enhancers, abstract and [0028] and [0038]. The reference teaches the use of permeation enhancers to help in increasing the rate at which the active substance permeates through skin, [0036]. The adhesive matrix comprises acrylate polymers which can be either a single Eudragit grade or mixtures of various Eudragit such as

Eudragit NE, Eudragit S, RL etc. see example IV and V on page 9. Tributyl citrate esters are disclosed to be used in formulation as permeation enhancers, [0060].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have replaced the adhesive polymeric matrix of WO with the adhesive polymeric matrix comprising acrylic polymer such as Eudragit NE along with permeation enhancers such as tributyl citrate esters used for transdermal application to skin as taught by Xlong et al. One of ordinary skill would be motivated to do so because Xlong teaches use of known acrylic polymers such as Eudragit NE along with permeation enhancers such as tributylcitrate esters increase the rate of permeation of active ingredients to skin once applied to skin. Therefore, one of ordinary skill would have reasonable expectation of success in obtaining a dermal composition comprising polymeric matrix materials such as Eudragit, citrate esters and aminolaevulinic acid crystals having the size ranges suggested by '765 which will provide a flexible polymer comprising ALA crystals such that the polymer matrix is stable and also easy to handle.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/05813 (WO '813) in view of US 6,280,765 to Gueret ('765) as applied to claims 1-6, 9 and 13-14 above, and further in view of GIERSKCKY et al. (WO 96/28412).

The references discussed above do not teach the claimed specific esters of aminolevulinic acid.

GIERSKCKY et al. discloses esters of 5-aminolevulinic acids. (same as claimed formula of instant claims 1 and 14) and their application in external and internal surfaces

of body, abstract. The reference teaches use of such esters in treatment of various abnormalities or disorders of skin or their epithelial organs, page 1, lines 9-10.The reference thus teaches the preparation and use of esters of laevulinic acid.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized the known specific esters of aminolevulinic acid as taught by '413 in the teachings of WO'813 and Guret because WO '813 teaches use of water soluble actives amino laevulinic acid for treatment of cutaneous conditions in dermal application and '765 teaches inclusion of water soluble and water soluble agents in transdermal patch in particulate form for controlled delivery of water soluble as well as water insoluble active agents simultaneously, and excellent adhesive power of the patch to the skin surfaces. Use of known esters of laevulinic esters into the known polymeric matrix used for dermal application to treat skin conditions would provide predictable results.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/

Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612